

Attorney Docket No: 3495.0059-06

PATENT

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In re Application of:

HUGHES BLAUDIN DE THE; AGNES  
MARCHIO; PIERRE TIOLLAIS; ANNE  
DEJEAN; NIGEL BRAND; MARTIN  
PETKOVICH; ANDREE KRUST; AND  
PIERRE CHAMBON

Serial No.: 07/649,342

Group Art Unit: 1812

Filed: February 1, 1991

Examiner: J. ULM

For: A NOVEL STEROID/THYROID  
HORMONE RECEPTOR-  
RELATED GENE  
INAPPROPRIATELY  
EXPRESSED IN HUMAN  
HEPATOCELLULAR  
CARCINOMA

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GROUP 1800

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

RESPONSE TO EXAMINER'S COMMUNICATION  
REGARDING STATEMENT OF AUTHORITY  
PURSUANT TO 37 C.F.R. 1.192(a)

This paper is filed in response to the Examiner's communication of July 10, 1996. The Examiner asserts that In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995), does not apply to the instant facts and maintains the rejection of claims 1-14, 24-34, 39-57, and 59 under 35 U.S.C. § 103 as allegedly being unpatentable over Petkovich et al. in view of Hauptmann et al. and Krust et al.

The Examiner states that the facts of the instant case are distinguished from those of Deuel. In particular, the Examiner alleges that Petkovich et al. disclose a part of the claimed DNA and the chromosomal location of the entire gene corresponding to that part of the claimed

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DNA. The Examiner goes on to state that the partial sequence disclosed is located downstream from the insertion site of the hepatitis B virus (HBV) genome in a human hepatoma and encodes a protein, which is part of the nuclear hormone receptor family. The rejection is "based upon a conclusion that the disclosure of a significant part of a DNA in conjunction with a motivation to isolate a complete DNA was sufficient to render that complete DNA *prima facie* obvious to one of ordinary skill." (Examiner's communication of July 10, 1996 at 2-3.)

Appellants respectfully disagree. The Examiner argues that Appellants did not "invent" the claimed DNA, but "... isolated the preexisting compound from a mixture of chemically related compounds." (Examiner's communication of July 10, 1996 at 3.) Appellants submit that it is well established in the law that non-naturally occurring biological compounds may constitute a patentable "invention" under 35 U.S.C. § 101. Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980). Here, Appellants claim an isolated and purified DNA sequence of the retinoic acid receptor, RAR- $\beta$ , which is not a product of nature. Prior to Appellant's discovery, this DNA sequence had not been isolated and purified. Thus, this constitutes an "invention" under 35 U.S.C. § 101 and the Examiner's assertion is without merit.

In addition, Appellants claim a chemical compound without any limitations as to the manner by which the chemical compound is obtained. Apparently, the Examiner tends to argue that the alleged novelty of the claimed compound is merely the "isolation" of the DNA sequence. However, the claims do not recite the mode of obtaining the claimed DNA sequence. To the contrary, the Examiner appears to be reading into the product claims an isolation step in order to serve his purpose. However, this purpose is not supported by the law. The court in Deuel held that the obviousness of a chemical entity must be based upon structural obviousness. In other words, a known chemical entity is required to render the claimed chemical entity obvious without regard to the method of isolating the chemical entity.

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At best, the cited prior art discusses DNA encoding RAR- $\alpha$ . However, as previously stated in the STATEMENT OF RELEVANT AUTHORITY, the proteins, RAR- $\alpha$  and RAR- $\beta$ , are structurally dissimilar. In addition, the DNA encoding these proteins are structurally dissimilar. No motivation is provided by the secondary references to modify the known partial DNA sequence of RAR- $\alpha$  to arrive at the claimed DNA.

In fact, Petkovich et al. merely discloses a partial DNA sequence of RAR- $\alpha$ . A copy of Figure 3C from Petkovich et al., which the Examiner relies upon to teach the partial nucleotide sequence, is set forth in Exhibit 1. A copy of the claimed DNA sequence is set forth in Exhibit 2. Appellants have highlighted the only portions of the nucleotide sequences, which are common to both the known sequence of Petkovich et al. and the claimed sequence. As can clearly be seen from these exhibits, Petkovich et al. teaches only 150 nucleotides common to the 1,281 nucleotide sequence of the claim. This gives only 11.7% homology ( $150/1281 \times 100$ ).

Accordingly, the disclosure of Petkovich et al. does not provide the requisite structural homology to render the claimed chemical entity obvious. Moreover, one having ordinary skill in the art would not been motivated to modify the known nucleotide sequence of Petkovich et al. In fact, to do so would have required the addition of 1,131 nucleotides.

The Examiner states that "modification" is not what is required here, but isolation of the gene. However, even if one would be motivated to isolate the gene, Appellants respectfully submit that the isolation of the DNA described in Petkovich et al. would result in a different sequence from the claimed sequence. For example, Appellants note in Exhibit 1 that the nucleotide sequences before and after the highlighted sequence differs from those claimed. Accordingly, even if the "isolation" step is properly read into the claim, which Appellants assert is not the case here, the isolation of the Petkovich et al. nucleotide sequence still does not

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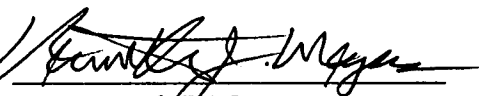
provide the claimed invention, but a different nucleotide sequence with little homology to the claimed nucleotide sequence.

Accordingly, Appellants respectfully request the reversal of the Examiner's rejection under 35 U.S.C. § 103.

If there are any other fees due in connection with the filing of this response, including any fees required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested, and the Commissioner is authorized to charge any related fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

By:   
Kenneth J. Meyers  
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Dated: September 27, 1996

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